41. (NEW) The method of claim 2 wherein the instantaneous respiration phase is a fraction of a revolution of a respiration cycle.

42. (NEW) The apparatus of claim 17 wherein the instantaneous respiratory phase is a fraction of a revolution of a respiratory cycle.

REMARKS

The Examiner has rejected claims 1-40 under 35 U.S.C. § 112. Claims 1-2, 9-10, 17-18, 25-26, 33-34 & 37-38 stand rejected under 35 U.S.C. § 102(e) in light of the disclosure of Banner et al (U.S. Patent No. 6,390,091). Claims 3-8, 12-15, 35-36 stand rejected under 35 U.S.C. § 103(a) over Banner et al. (U.S. Patent No. 6,390,091) in view of Schmidt (U.S. Patent No. 6,186,142). For the following reasons, Applicant requests that the Examiner withdraw the rejections.

A. Rejections under 35 U.S.C. § 112, First Paragraph

The standard for determining whether the written description requirement has been met has been stated as follows:

> Although [the applicant] does not have to describe exactly the subject matter claimed, ... the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. ... The test for sufficiency of support ... is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ.2d 1111, 1116 (Fed. Cir. 1991) (citations and quotations omitted). *See also Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ.2d 1767 (Fed. Cir. 1993). "An inventor is not required to describe every detail of his invention." *In re Hayes Microcomputer Products Inc. Patent Litigation*, 25 USPQ.2d 1241, 1246 (Fed. Cir. 1992). The requirements of section 112,

first paragraph are satisfied when "one skilled in the relevant art would understand what is intended and know how to carry it out." *Id.*

The Examiner's rejection suggests that the application lacks sufficient information to convey to one skilled in the art of "establishing or equating any range of revolution values to being indicative of what is commonly understood in the art as 'respiratory phase'" because "respiratory phase" would be understood by those skilled in the art to include "inspiration, expiration, intervening pause or post-expiration/pre-inspiration." For this reason, the Examiner deems that the application does not convey to one skilled in the art that the inventor had possession of the claimed invention. Applicant disagrees.

In a manner that would be understood by one skilled in the art, the application specifically and clearly describes how to identify features of respiratory phase by fractions of a revolution. In this regard, the specification describes an example of quantifying a fractional portion of respiration as it relates to the construction of fuzzy inference rules as follows:

> The general method for developing and using these additional fuzzy inference rules for the effort signal is the same as the method described in International Publication Nos. WO 98/12965 and WO 99/61088. Generally, various features, such as the point of start of inspiration, are identified on a graph of effort versus phase, and for each phase, corresponding fuzzy rules are developed. For example, a suitable rule for the point "start of inspiration" could be "effort signal is small and the second derivative of the effort signal with respect to time is large positive." Membership functions, would cause that rule to be maximally activated at or near the start of inspiration. Preferably, the exact phase at the moment of maximal activation should be determined empirically. In the current example, the maximum activation will be at a phase shortly after the actual moment of start of inspiration, say 0.05 revolutions, and this is the best phase to associate with the rule. The more features that are identified and assigned a rule and a phase, the smoother will be the resultant determination of phase.

Specification p. 8, lines 11-20 (emphasis added). Applicant submits that given this written description, including the example, an individual skilled in the art would understand from the specification how to equate any fraction or range of fractions of a revolution, i.e. a fraction of a cycle, with the features associated with inspiration,

expiration, intervening pause or post-expiration/pre-inspiration since individuals skilled in the art would be able to recognize these features from the described graph. Thus, individuals skilled in the art would recognize that the inventors were in possession of the invention as claimed. As such, Applicant requests that the Examiner withdraw the rejection.

B. Rejections under 35 U.S.C. § 112, Second Paragraph

With regard to the rejections in paragraphs 5 and 6 of the Office Action, the identified claims have been amended to include the features suggested by the Examiner as essential.

Applicant has also addressed the antecedent basis rejections of paragraphs 7 and 8. Claims 1, 9, 17, 25, 33, and 37 have been amended to amend the "desired ventilation" element. By amendment to claims 17 and 37 the antecedent basis issue with regard to "instantaneous respiratory phase" has been resolved.

The Examiner has also rejected claims on the proposition that a meaning for "respiratory phase" has been claimed that is repugnant to that terminology. Applicant does not agree with the Examiner's assessment. In this regard, under 35 U.S.C. § 112, second paragraph, only if the scope of the invention may not be determined with a reasonable degree of certainty from the language of the claim is rejection appropriate. *In re Wiggins*, 488 F.2d 538, 179 U.S.P.Q. 421 (C.C.P.A. 1973). Such a determination must take into account (1) the content of the specification; (2) prior art disclosures; and (3) the interpretation that might be given by one of ordinary skill in the pertinent field. M.P.E.P. § 2173.02.

The Examiner' rejection suggests that defining "respiratory phase" as a fraction of a revolution is repugnant to the "accepted meaning" of respiratory phase which is "inspiration, expiration, intervening pause or post-expiration/pre-inspiration."[1] By this rejection, the Examiner proffers one view of the term "phase" to the implied exclusion of

[1] This interpretation recognizes that "phase" can be understood as "any of the stages ... in any series or cycle of changes." Webster's New World Dictionary, 3rd College Edition, Simon &

any others, consistent or otherwise. While different stages of the respiratory cycle may be recognized by the specific labels identified by the Examiner, that alone does not mean that defining phase by a fractional revolution in a dependent claim is contradictory to such an understanding.[2] Rather, in light of the disclosure of the specification that demonstrates how these stages or features can be equated with fractions of a revolution, the features identified by the Examiner ("inspiration, expiration, intervening pause or post-expiration/pre-inspiration") can only be viewed as consistent with the fractional revolution terminology.

As the Examiner must concede, and those skilled in the art would recognize, respiration is a cycle, i.e. a revolution. Moreover, the meaning of the term "phase" can be understood to include "the fractional part of a cycle through which an oscillation ... has advanced, measured from an arbitrary starting point." Webster's New World Dictionary, 3rd College Edition, Simon & Schuster 1991. As previously identified, the application specifically discloses the details of a method by which the stages or features of respiratory phase can be equated with revolutions or fractions of a revolution. Specification p. 8, lines 11-20. Thus, defining respiratory phase to include fractions of a revolution is not at all repugnant to identifying respiratory phase by its discrete stages. Accordingly, the claims fully satisfy the requirements of § 112, second paragraph.

C. Rejections under 35 U.S.C. § 102

An invention is anticipated under § 102 if the same device, including all the claim limitations, is shown in a single prior art reference. *Richardson v. Suzuki Motor Co. Ltd.* 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). Every element of the claimed invention must be literally present, arranged as in the claim. *Perkin-Elmer Corp v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir.), *cert. denied*, 469 U.S. 857 [225 USPQ 792] (1984); *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771-72, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 [224 USPQ 520] (1984). The identical invention must be shown in as complete detail as is

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Schuster 1991.

[2] It is not improper to submit claims that further limit a parent claim. See 37 C.F.R. § 1.75(c).

contained in the patent claim. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 756 F.2d 1556,1560, 225 USPQ 253, 256 (Fed. Cir. 1985); *Connell v. Sears, Roebuck & Co*, 722 F.2d 1542, 1548, 220 USPQ 193,198 (Fed. Cir. 1983).

The Examiner contends that Banner et al. (U.S. 6,390,091) anticipates the invention of claims 1-2, 9-10, 17-18, 25-26, 33-34 and 37-38. However, an important feature defined by the independent claims 1, 17, 33 and 37 of the application is not literally or inherently present in the device of Banner et al. To this end, the present claims define methods and apparatus that include a determination of instantaneous respiratory phase or instantaneous respiration phase by analysis of both respiratory airflow and respiratory effort.

The problem addressed by the Applicant in the present invention is to provide ventilatory assistance in phase ("synchronized") with a patient's respiratory efforts. That is, the invention is particularly directed towards ventilation for patients who breath spontaneously, though inadequately. At one level, this means providing higher pressure(s) when the patient breathes in and lower pressure(s) when the patient breathes out. This is a more complicated problem than it sounds. The precise moment when the transition between inspiration and expiration occurs is difficult to detect. It can also be difficult to define if the patient breathes irregularly. If the ventilator is not synchronized with the patient, the patient might feel like they are fighting the device. For example, the patient might start to breath in, but the ventilator still "thinks" they are breathing out and so continues to provide low pressure(s) associated with expiration. Hence, the patient might feel like they cannot get enough air.

There can be a particular problem with ventilators that use flow sensors in the air delivery circuit to synchronize ventilator pressure cycling. If there is a leak in the air delivery circuit, for example, due to a leak between a mask and a patient's face, the flow sensor may detects an inaccurate total flow (leak flow + respiratory flow). This over estimation of flow interferes with an accurate assessment of the patient's respiratory cycle.

A similar problem can occur with using a pressure transducer in an air delivery

conduit to synchronize. In the presence of a severe leak, the pressure transducer would read a low value, otherwise indicative of patient inspiration even though the patient might be exhaling. Thus, the device would reach a wrong conclusion about whether the patient is breathing in or out.

The patent to Banner et al. includes examples of these problems. Banner et al. discuss triggering, i.e. switching from an expiratory pressure level to an inspiratory pressure level, using two different methods, either "pressure or flow-by triggering." Banner et al., col. 27, lines 17-19. In the Banner et al. device, a pressure transducer is in the air delivery circuit near the blower or alternatively, located at the end of an endotracheal tube inserted within the patient's trachea. Banner et al., col. 30, line 56 - col. 31, line 9. The trigger is changed based upon whether the detected pressure is below or above a preset pressure level. Banner et al., col. 29, lines 26-40.

It is noteworthy, that the Banner et al. device *does not trigger based upon an analysis of flow*. Rather, it criticizes flow-based triggering as being sub-par to the use of pressure-based triggering. Banner et al., col. 28, lines 12-42. Thus, it cannot be said to anticipate the invention defined by the present claims. The claims all define methods and apparatus that determine instantaneous respiratory phase or instantaneous respiration phase by analysis of <u>both respiratory airflow and respiratory effort</u>. This aspect of the invention is summarized in the specification at p. 4, line 1 - p. 5 line 19.

In addition, with regard to the invention of amended claims 2, 18, 34 and 38, the device of Banner et al. does not trigger based upon a detection of respiratory effort from a <u>leak independent effort sensor</u>. In this regard, the tracheal pressure detection device of Banner et al. is not a device for the detection of respiratory effort that is immune from errors associated with leak. To this end, the pressure-sensing device of Banner et al. being in the trachea portion of the patient's airway may still be subject to errors in the presence of a leak. For this reason, respiratory effort detection devices outside the airway circuit are considered more accurate. For example, Essen-Moller (US Patent 5,810,741), which states:

> Several methods are known that attempt to measure the degree of effort a patient is exerting in an attempt to breathe. The degree of effort

> exerted in the attempt to breathe is identified as "respiratory effort". Such methods include applying stretch sensitive belts (similar to strain gauges) to the outside of the abdomen, or the application of electrodes to the chest to measure changes in impedance. These approaches are cumbersome and inaccurate. The most accurate technique for measuring respiratory effort is through measuring air pressure changes in the esophagus or stomach. An effort to inhale results in an air pressure drop in the esophagus and trachea, and in a pressure increase in the stomach. This happens even though real inspiration and movement of air from the ambient room to the patient's lungs may not necessarily follow due to, for example, pharyngeal obstruction. An effort to exhale causes analogous events, but in the opposite directions (that is, an air pressure increase in the esophagus and trachea, and a drop in the stomach). When no effort to breathe occurs, the air pressure in these areas will remain constant.

Essen-Moller, col. 1, line 43 - col. 2, line 5.

As noted in the current specification, the chosen effort sensors are immune to errors associated with leak in the airflow measurement. Specification, p. 4, line 35 - p. 5, line 1. The amended claims 2, 18, 34 and 38 each define that the effort sensors are leak independent. Moreover, Banner et al. does not disclose either a suprasternal notch sensor, an esophageal pressure effort sensor or an electromyograph as required by these claims. While the Examiner has relied on element 100 from Fig. 10 of Banner et al. for the proposition that an "esophageal pressure effort sensor" is disclosed, the element 100 is actually an endotracheal pressure sensor. Banner et al. states that "the preferred pressure sensor 100 may be comprised of a disposable endotracheal tube provided by Mallinckrodt Critical Care having a pressure sensor 100 embedded within a lumen in the sidewall of the endotracheal tube 54 near the distal end 56 of the endotracheal tube 54." Banner et al., col. 29, lines 10. As evidenced by the above excerpt from Essen-Moller, there is an important distinction between the esophagus as part of the digestive system and the trachea as part of the patient's airway. The preferred device of Banner et al. includes an endotracheal tube inserted into the patient's mouth and into the patient's trachea so that the distal end of the endotracheal tube is disposed in the trachea before it branches into the mainstream bronchi that leads to the patient's lung.

With regard to amended independent claims 33 and 37 and respective dependent claims 34-36 and 38-40, applicant has made clear that the phase determined by both the respiratory airflow and respiratory effort is represented as a fraction of a revolution. This feature is not disclosed in the patents to Banner et al. or Schmidt et al.

Applicant notes that the Examiner has rejected claims 27 and 32 based on the conclusion that the language therein does not positively recite any function. Applicant disagrees. Parent claims 20 and 22 from which claims 27 and 32 depend, clearly state that the processor evaluates fuzzy inference rules. Applicant submits that this is a positively recited function. Furthermore, this function is further limited by the positively defined rules of dependent claims 27 and 32. Under the circumstances, Applicant requests that the Examiner withdraw the rejections with regard to these claims. Moreover, to the extent that the Examiner deems the apparatus of Banner et al. to be *capable* of this function and those defined by claims 19-32 and 39-40, such a capability is being assumed by the Examiner. As it relates to a rejection under § 102, Banner et al. must literally disclose that the apparatus is performing the claimed functions. Banner et al. makes no such disclosure.

For these reasons, Applicant requests that the Examiner withdraw the rejection under § 102.

D. Rejections under 35 U.S.C. § 103

For the reasons stated above with regard to the independent claims of the application, since Banner et al. does not disclose determining instantaneous phase by an analysis of both respiratory airflow and respiratory effort. Similarly, the patent to Schmidt et al. does not disclose triggering based upon an analysis of both respiratory airflow and respiratory effort. Schmidt et al. only disclose a flow triggering respiration sensor. Schmidt et al., col. 9, line 28 - col. 10, line 9. Moreover, in light of Banner et al.'s statements to the effect of the "inherent inadequacy" of flow based triggering, Banner et al., col. 28, line 34, there can not be said to be a suggestion to combine the references because Banner et al. teach away from the use of flow based triggering.

When the prior art can be said to teach away from an invention, there cannot be said to be a motivation, suggestion or teaching to combine the references. *Tec Air Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). Accordingly, Applicant submits that the defined invention of claims 1 -40 is not obvious.

E. Request for Interview

If the Examiner intends to continue to rely upon the existing rejections, Applicant requests that the Examiner contact the undersigned to arrange for an interview.

Respectfully submitted,
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APPENDIX A

(marked-up version of claim amendments)

1. (AMENDED) A method of providing synchronized ventilatory support to a patient comprising the steps of:

providing apparatus to deliver ventilatory support to a patient;

determining the patient's instantaneous respiration phase at least in part from both measured respiratory airflow and a signal from a respiratory effort sensor,

calculating a desired pressure value using the determined phase and a desired ventilation pressure amplitude; and

delivering ventilation to said patient in accordance with said desired pressure value.

2. (TWICE AMENDED) The method of claim 1 wherein said respiratory effort sensor is selected from a group of effort sensors that are independent of a leak in airflow that may affect respiratory airflow measurement including:

(a) a suprasternal notch sensor;

(b) an esophageal pressure effort sensor; and

(c) an electromyograph.

3. (AMENDED) The method of claim ~~1~~ 41 wherein ~~said~~ the phase determining step comprises evaluating fuzzy inference rules relating to said signal from said respiratory effort sensor.

4. The method of claim 3 wherein said phase determining step further comprises evaluating fuzzy inference rules relating to the rate of change of said signal from said respiratory effort sensor.

5. The method of claim 4 wherein said phase determining step further includes the sub-step of evaluating fuzzy logic inference rules relating to the measured respiratory airflow.

6. The method of claim 5 wherein said phase determining step further includes the sub-step of evaluating fuzzy logic inference rules relating to the rate of change of the measured respiratory airflow.

7. The method of claim 1 wherein said phase determining step further includes the sub-step of evaluating fuzzy logic inference rules relating to the measured respiratory airflow.

8. The method of claim 7 wherein said phase determining step further includes the sub-step of evaluating fuzzy logic inference rules relating to the rate of change of the measured respiratory airflow.

9. (AMENDED) The method of claim 1 wherein the desired ventilation pressure amplitude is varied between ~~has~~ a non-zero minimum value and a maximum value.

10. The method of claim 9 wherein said step of calculating a desired pressure value includes deriving an error value that is a function of the difference between calculated patient ventilation and a target value.

11. (AMENDED) The method of claim 4 wherein said fuzzy inference rules include at least one rule selected from a group of rules including:

(a) If the effort signal is zero and increasing fast, then ~~the~~ phase is about 0 revolutions;

(b) If the effort signal is medium and increasing moderately, then ~~the~~ phase is about 0.2 revolutions;

(c) If the effort signal is large and decreasing fast, then ~~the~~ phase is about 0.5 revolutions; and

(d) If the effort signal is medium and decreasing moderately, then ~~the~~ phase is about 0.7 revolutions.

12. The method of claim 4 wherein said fuzzy inference rules include a rule in which the start of inspiration is associated with approximately zero respiratory effort which is increasing fast.

13. The method of claim 4 wherein said fuzzy inference rules include a rule in which mid-inspiration is associated with medium respiratory effort which is increasing moderately.

14. The method of claim 4 wherein said fuzzy inference rules include a rule in which the beginning of expiration is associated with large respiratory effort which is decreasing fast.

15. The method of claim 4 wherein said fuzzy inference rules include a rule in which mid-expiration is associated with medium respiratory effort which is decreasing moderately.

16. (TWICE AMENDED) The method of claim 6 wherein said fuzzy inference rules include at least one rule selected from a group of rules including:

(a) If the airflow is zero and increasing fast, then ~~the~~ phase is about 0 revolutions;

(b) If the airflow is large positive and steady, then ~~the~~ phase is about 0.25 revolutions;

(c) If the airflow is zero and falling fast, then ~~the~~ phase is about 0.5 revolutions;

(d) If the airflow is large negative and steady, then ~~the~~ phase is about 0.75 revolutions;

(e) If the airflow is zero and steady and the 5-second low-pass filtered absolute value of the respiratory airflow is large, then ~~the~~ phase is about 0.9 revolutions;

(f) If the airflow is positive and the phase is expiratory, then ~~the~~ phase is about 0.1 revolutions;

(g) If the airflow is negative and the phase is inspiratory, then ~~the~~ phase is about 0.6 revolutions;

(h) If the 5-second low-pass filtered absolute value of the respiratory airflow is small, then ~~the~~ phase in the respiratory cycle is increasing at a fixed rate equal to the patient's expected respiratory rate; and

(i) If the 5-second low-pass filtered absolute value of the respiratory airflow is large, then the phase in the respiratory cycle is increasing at a steady rate equal to the existing rate of change of phase, low-pass filtered with a time constant of 20 seconds.

17. (AMENDED) An apparatus for providing synchronized ventilatory support to a patient comprising:

at least one sensor to generate a respiratory effort signal;

at least one sensor to generate a respiratory airflow signal;

a processor in communication with the effort signal and the airflow signal for analyzing both the respiratory airflow signal and ~~said~~ the effort signal to determine ~~the~~ instantaneous respiratory phase of the patient and to generate a ~~desired~~ pressure request signal as a function of said instantaneous respiratory phase and a ~~desired~~ ventilation pressure amplitude; and

a servo-controlled blower to provide pressurized air to said patient in accordance with said pressure request signal.

18. (TWICE AMENDED) The apparatus of claim ~~17~~ 42 wherein said at least one sensor is an effort sensor from a group of effort sensors that are independent of a leak in airflow that may affect respiratory airflow measurement including:

(a) a suprasternal notch sensor;

(b) an esophageal pressure effort sensor; and

(c) an electromyograph.

19. The apparatus of claim 17 wherein said processor evaluates fuzzy inference rules relating to said respiratory effort signal.

20. The apparatus of claim 18 wherein said processor evaluates fuzzy inference rules relating to the rate of change of said respiratory effort signal.

21. The apparatus of claim 20 wherein said processor evaluates fuzzy logic inference rules relating to the respiratory airflow.

22. The apparatus of claim 21 wherein said processor evaluates fuzzy logic inference rules relating to the rate of change of the respiratory airflow.

23. The apparatus of claim 17 wherein said processor evaluates fuzzy logic inference rules relating to the respiratory airflow.

24. The apparatus of claim 23 wherein said processor evaluates fuzzy logic inference rules relating to the rate of change of the respiratory airflow.

25.(AMENDED) The apparatus of claim 17 wherein the ~~desired~~ ventilation pressure amplitude is varied between ~~has~~ a non-zero minimum value and a maximum value.

26. (AMENDED) The apparatus of claim 25 wherein the generation of said ~~desired~~ pressure request signal includes deriving an error value that is a function of the difference between calculated patient ventilation and a target value.

27. (AMENDED) The apparatus of claim 20 wherein said fuzzy inference rules include at least one rule selected from a group of rules including:

(a) If the effort signal is zero and increasing fast, then ~~the~~ phase is about 0 revolutions;

(b) If the effort signal is medium and increasing moderately, then ~~the~~ phase is about 0.2 revolutions;

(c) If the effort signal is large and decreasing fast, then ~~the~~ phase is about 0.5 revolutions; and

(d) If the effort signal is medium and decreasing moderately, then ~~the~~ phase is about 0.7 revolutions.

28. The apparatus of claim 20 wherein said fuzzy inference rules include a rule in which the start of inspiration is associated with approximately zero respiratory effort which is increasing fast.

29. The apparatus of claim 20 wherein said fuzzy inference rules include a rule in which mid-inspiration is associated with medium respiratory effort which is increasing moderately.

30. The apparatus of claim 20 wherein said fuzzy inference rules include a rule in which the beginning of expiration is associated with large respiratory effort which is decreasing fast.

31. The apparatus of claim 20 wherein said fuzzy inference rules include a rule in which mid-expiration is associated with medium respiratory effort which is decreasing moderately.

32. (TWICE AMENDED) The apparatus of claim 22 wherein said fuzzy inference rules include at least one rule selected form a group of rules including:

(a) If the airflow is zero and increasing fast, then ~~the~~ phase is about 0 revolutions;

(b) If the airflow is large positive and steady, then ~~the~~ phase is about 0.25 revolutions;

(c) If the airflow is zero and falling fast, then ~~the~~ phase is about 0.5 revolutions;

(d) If the airflow is large negative and steady, then ~~the~~ phase is about 0.75 revolutions;

(e) If the airflow is zero and steady and the 5-second low-pass filtered absolute value of the respiratory airflow is large, then ~~the~~ phase is about 0.9 revolutions;

(f) If the airflow is positive and the phase is expiratory, then ~~the~~ phase is about 0.1 revolutions;

(g) If the airflow is negative and the phase is inspiratory, then ~~the~~ phase is about 0.6 revolutions;

(h) If the 5-second low-pass filtered absolute value of the respiratory airflow is small, then ~~the~~ phase in the respiratory cycle is increasing at a fixed rate equal to the patient's expected respiratory rate; and

(i) If the 5-second low-pass filtered absolute value of the respiratory airflow is large, then ~~the~~ phase in the respiratory cycle is increasing at a steady rate equal to the existing rate of change of phase, low-pass filtered with a time constant of 20 seconds.

33. (AMENDED) A method of providing synchronized ventilatory support to a patient comprising the steps of:

providing apparatus for ventilatory support to a patient comprising a flow sensor and a respiratory effort sensor;

determining the patient's instantaneous respiration phase represented as a fraction of a revolution of a respiratory cycle at least in part from a signal from ~~a~~ the respiratory effort sensor and a signal from the flow sensor,

calculating a ~~desired~~ pressure value using the determined phase and a ~~desired~~ ventilation pressure amplitude; and

delivering ventilation to said patient in accordance with said ~~desired~~ pressure value.

34. (TWICE AMENDED) The method of claim 33 wherein said respiratory effort sensor is selected from a group of effort sensors that are independent of a leak in airflow that may affect respiratory airflow measurement including:

(a) a suprasternal notch sensor;

(b) an esophageal pressure effort sensor; and

(c) an electromyograph.

35. The method of claim 34 wherein said phase determining step comprises evaluating fuzzy inference rules relating to said signal from said respiratory effort sensor.

36. The method of claim 35 wherein said phase determining step further comprises evaluating fuzzy logic inference rules relating to the rate of change of said signal from said respiratory effort sensor.

37. (AMENDED) An apparatus for providing synchronized ventilatory support to a patient comprising:

at least one sensor to generate a respiratory effort signal;

at least one sensor to generate a respiratory airflow signal;

a processor in communication with the effort signal and airflow signal for analyzing both said effort signal and said airflow signal to determine ~~the~~ instantaneous respiratory phase of the patient represented as a fraction of a revolution of a respiratory cycle and to generate a desired pressure request signal as a function of said instantaneous respiratory phase and a desired ventilation pressure value; and

a servo-controlled blower to provide pressurized air to said patient in accordance with said pressure request signal.

38. (TWICE AMENDED) The apparatus of claim 37 wherein said at least one sensor is an effort sensor from a group of effort sensors that are independent of a leak in airflow that may affect respiratory airflow measurement including:

(a) a suprasternal notch sensor;

(b) an esophageal pressure effort sensor; and

(c) an electromyograph.

39. The apparatus of claim 38 wherein said processor evaluates fuzzy inference rules relating to said respiratory effort signal.

40. The apparatus of claim 39 wherein said processor evaluates fuzzy inference rules relating to the rate of change of said respiratory effort signal.

41. (NEW) The method of claim 2 wherein the instantaneous respiration phase is a fraction of a revolution of a respiration cycle.

42. (NEW) The apparatus of claim 17 wherein the instantaneous respiratory phase is a fraction of a revolution of a respiratory cycle.